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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants : Lorna W. Role et al.  
Serial No. : 09/312,596 Examiner: S. Gucker  
Filed : May 14, 1999 Art Unit: 1647  
For : A-FORM OF CYTOPLASMIC DOMAIN OF nARIA (CRD-  
NEUREGULIN) AND USES THEREOF

1185 Avenue of the Americas  
New York, New York 10036  
December 5, 2001

Hon. Commissioner for Patents  
P.O. Box 2327, Arlington, Virginia 22202

Sir:

COMMUNICATION IN RESPONSE TO JULY 5, 2001 RESTRICTION  
REQUIREMENT AND PETITION FOR A FOUR-MONTH EXTENSION OF TIME

This Communication is submitted in response to the July 5, 2001 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the July 5, 2001 Office Action was originally due on August 5, 2001. Applicants hereby request a four-month extension of time from August 5, 2001 to December 5, 2001. The fee for a four-month extension of time is SIX HUNDRED NINETY-FIVE DOLLARS (\$695.00) for a small entity. Applicants have previously established small entity status. Thus, a response to the July 5, 2001 Office Action is now due December 5, 2001. Accordingly, this Amendment is being timely filed.

REMARKS

In the Office Action, the Examiner restricted pending claims 1-29 to one

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of the following allegedly distinct inventions under 35 U.S.C. §121:

- I. Claims 1-9 and 25-29, drawn to an assay for diagnosing whether a subject has or is predisposed to a disease associated with the neuregulin receptor;
- II. Claim 10, drawn to a method of maintaining synaptic connections associated with the nARIA receptor;
- III. Claims 11-16 and 19, drawn to a method for treating disease associated with the nARIA receptor in a subject;
- IV. Claims 17 and 18, drawn to a method for inducing neuronal regeneration using a composition comprising nARIA; and
- V. Claims 20-24, drawn to assays of ligand binding.

The Examiner stated that if applicants elect Group I or Group III, a disease or syndrome must also be elected (below). Therefore, the Examiner required a secondary restriction under 35 U.S.C. §121 to one of the following diseases or syndromes:

- A. Breast Cancer;
- B. Prostate Cancer;
- C. Brain Cancer;
- D. Ovarian Cancer;
- E. Alzheimer's Disease;
- F. Parkinson's Disease;

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- G. Tourette's Syndrome;
- H. Amyotrophic lateral sclerosis;
- I. Pick's Disease;
- J. Myasthenia gravis; and
- K. Senility.

The Examiner alleged that each disease or syndrome named above is independent and distinct, one from the other, because their searches are non-overlapping, resulting in an undue search burden.

In response, applicants hereby elect with traverse, claims 20-24, drawn to assays of ligand binding, for prosecution at this time.

Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

The inventions of Groups I-V are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subject matter claimed. The inventions of Groups I-V are all drawn to nARIA-related uses. Applicants therefore maintain that Groups I-V are not independent and restriction is not proper.

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Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups I-IV would not require a serious burden once the prior art relevant to Group V has been identified.

Accordingly, there would be no serious burden on the Examiner to examine Groups I-V together. Hence, the Examiner must examine these Groups on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121, and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

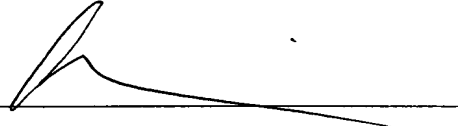
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed \$695.00 fee for a four-month extension of time, is deemed necessary in connection with the filing of this

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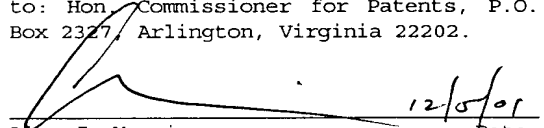
Communication. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Hon. Commissioner for Patents, P.O. Box 2327, Arlington, Virginia 22202.



Alan J. Morrison  
Reg. No. 37,399

12/5/01  
Date